

**REMARKS**

Claims 4, 6, 8, 10, and 16-18 are all the claims pending in the application. Claims 8 and 10 were previously withdrawn from consideration.

Claims 4 and 17 have been amended to recite that the bacteria are present in the composition “in an amount effective to stimulate mucosal immunity.” Support for the amendments may be found, for example, in the abstract. Claim 4 has further been amended to delete the phrase “capable of stimulating mucosal immunity, and is” for clarification.

Claim 18 has been amended to recite “in an amount effective to promote human IgA production in mucosae.” Support for this amendment can be found, for example, at page 13, line 8 bridging page 14, line 11 of the specification.

Thus, no new matter has been added.

**I. Response to Objections to the Specification Under 35 U.S.C. § 132 (a)**

At page 2 of the Office Action, the Examiner objects to the specification under 35 U.S.C. § 132 (a) because it allegedly introduces new matter into the disclosure.

In particular, the Examiner asserts that the basis for the amendment, re-classifying the claimed *Lactobacillus plantarum* b0240 strain as *Lactobacillus pentosus* is unclear from Bringel et al. The Examiner requires Applicants to cancel the alleged new matter or provide evidence showing why the claimed *Lactobacillus plantarum* b0240 strain was determined to be *Lactobacillus pentosus*.

As a preliminary matter, Applicants amend the paragraph at page 3, line 3 of the specification herein for clarification and to correct the spelling of Bringel et al.

With regard to the merits of the objection, the Examiner acknowledges that Bringel teaches that the *Lactobacillus plantarum* phylogenetic subgroup is reclassified into three species

(i.e., *Lactobacillus plantarum*, *Lactobacillus pentosus* and *Lactobacillus paraplantarum*). See also Bringel, page 1629, 1<sup>st</sup> and 2<sup>nd</sup> column. However, the Examiner requires evidence showing why the claimed *Lactobacillus plantarum* b0240 strain was determined to be *Lactobacillus pentosus*.

In response, Applicants submit herewith a Supplemental Declaration under 37 C.F.R. § 1.132 (Appendix 2) which shows the results of an analysis of the *recA* gene of *Lactobacillus plantarum* b0240 strain as compared to the *recA* gene of *Lactobacillus plantarum*, *Lactobacillus pentosus*, and *Lactobacillus paraplantarum*.

The Supplemental Declaration, submitted by Yoshito Tajiri, presents the results of a study clarifying the issue of whether *Lactobacillus plantarum* ONRIC b0240 belongs to *Lactobacillus pentosus* subspecies *plantarum* or *Lactobacillus plantarum* subspecies *argenteratensis*.

In the Declaration, Tajiri analyzed and determined the partial base sequence of the *recA* gene and then subjected the sequence to molecular phylogeny analysis by Neighbor-Joining method CLUSTAL W software. See pages 4-6 of Supplemental Declaration (Appendix 2). The molecular phylogenetic data clearly shows that b0240 belongs to *Lactobacillus pentosus*. See page 7 of Supplemental Declaration (Appendix 2).

Accordingly, *Lactobacillus plantarum* ONRIC b0240 has been reclassified as *Lactobacillus pentosus*.

In view of the above, withdrawal of the objection to the specification is respectfully requested.

**II. Response to Claim Rejections Under 35 U.S.C. 112, Second Paragraph**

At page 2 of the Office Action, claims 4, 6 and 16-18 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking adequate written description. Specifically, the Examiner asserts that in view of Bringel et al., Applicants have not specifically indicated the basis for the reclassification of *Lactobacillus plantarum* b0240 strain to *Lactobacillus pentosus*.

In response, Applicants submit that the Supplemental Declaration (Appendix 2) clearly shows that *Lactobacillus plantarum* ONRIC b0240 has been reclassified as *Lactobacillus pentosus* for the same reasons discussed above in response to the objection to the specification.

Withdrawal of the rejection is respectfully requested.

**III. Response to Rejection of Claims 4, 6 and 16-18 Under 35 U.S.C. § 102/103**

At page 3 of the Office Action, claims 4, 6 and 16-18 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ikenaga et al. (Milk Science, 2002, 51: 27-32, hereinafter Ikenaga) or Perdigon et al. (J. Dairy Sci., 1999, 82:1108-1114, hereinafter Perdigon) or Herias et al. (Clin. Exp. Immunol., 1999, 116:283-290, hereinafter Herias), for reasons of record.

Specifically, the Examiner asserts that the cited references each disclose a *Lactobacillus plantarum* strain that appears to be identical to the presently claimed strains. Further, the Examiner states that although not identical to the present strains, the reference strains stimulate mucosal immunity and would inherently possess the same characteristics as the claimed microorganisms, rendering obvious the presently claimed invention.

The Examiner also alleges that since the claims are directed to a food or beverage composition or pharmaceutical compositions comprising a specific strain of *Lactobacillus plantarum*, the stimulation of mucosal immunity could be due to ingredients in the composition

rather than to the presence of the recited strains. Additionally, the Examiner asserts that there is no designated concentration of the *Lactobacillus plantarum* stains of interest in the claimed composition.

Without acquiescing to the merits of the rejection, Applicants amend claims 4 and 17 to recite that the bacteria are present in the composition “in an amount effective to stimulate mucosal immunity.” Further, Applicants amend claim 18 to recite that the bacteria are present “in an amount effective to promote human IgA production in mucosae.” In view of these amendments, none of Ikenaga, Perdigon, or Herias anticipates Applicants’ presently claimed invention.

With respect to the Examiner’s contention that the claimed strains, if not anticipated by the cited references are rendered obvious, Applicants respectfully disagree for the following reasons.

The Examiner asserts that (1) it is unclear that immunostimulation benefits are effective in the absence of a threshold concentration of bacteria in the composition, and (2) the stimulation of mucosal immunity could be due to ingredients in the composition rather than the recited strains such that no clear correlation exists between the material having the unexpected immunostimulating properties as disclosed in the Declaration of March 13, 2009 and the claimed composition.

With regard to (1), Applicants refer the Examiner to the specification, which discloses the IgA production-inducing capabilities of the claimed lactic acid bacteria, *in vivo*, using concentrations of the cells other than the alleged “threshold concentration” of  $2.0 \times 10^9$  cells/mL. See page 46, lines 15-25 under Example 3, and pages 47-55 of the specification. In Example 3, bacterial cells were suspended in a physiological saline to achieve a concentration of  $4.0 \times 10^9$

CFU/mL (viable cells) for oral administration. See page 47, lines 18-21 of the specification. Further, the suspension of the lactic acid bacteria (viable cells) prepared for oral administration, was further diluted to achieve a concentration of  $10^7$  CFU/ml (turbidity: 0.275 at 660 nm), and the resulting cell suspension was autoclaved and then ultrasonicated to obtain non-viable cells. See page 51, lines 1-9 of the specification. In view of the above, it is clear that benefits of human mucosal immunostimulation are effective at multiple concentrations of bacteria in addition to the alleged “threshold concentration.”

With regard to (2), Applicants submit that it would be clear to one of ordinary skill in the art, based on the disclosure in the specification, that the lactic acid bacteria are capable of providing excellent immunostimulation effects and that an edible carrier (as recited in present claim 4) and/or pharmaceutically acceptable excipient or diluent (as recited in present claims 17 and 18) are inert in the claimed composition.

Regarding Applicants’ Declaration of March 13, 2009, the Examiner admits that at the concentration of  $2.0 \times 10^9$  cells/mL, it is apparent from the presented data that the claimed strains show unexpected results over the strain 299v of Herias. However, the Examiner argues that the Declaration does not provide a comparison of the claimed strains vis-à-vis *Lactobacillus plantarum* ONC141 of Ikenaga.

In response, Applicants provide comparative data, in Rule 132 Declaration form (Appendix 1), demonstrating that the instantly claimed strains possess an unexpectedly superior property of promoting IgA production and stimulating mucosal immunity. Specifically, a comparison vis-à-vis *Lactobacillus plantarum* b0239 and b0240 of the present invention and *Lactobacillus plantarum* ONC141 of Ikenaga is set forth in the Declaration. As depicted in Table I, only *Lactobacillus plantarum* strains ONRIC b0239 (FERM BP-10064) and ONRIC

b0240 (FERM BP-10065), as claimed, stimulate IgA production to an S.I. value of 5 or more. On the other hand, the IgA S.I. value of *Lactobacillus plantarum* ONC141 of Ikenaga is 1.7.

Accordingly, the instantly claimed strains possess unexpectedly superior IgA-stimulating activity vis-à-vis the strains of the cited references, and such is probative of the non-obviousness of the claimed invention. It is well-settled that a demonstration of unexpected results, or unexpected superiority of a particular result or property, may rebut a finding of obviousness. Applicants respectfully submit that in view of such unexpectedly superior properties of the instantly claimed invention, the cited references, taken alone or in combination, do not render obvious Applicants' claimed invention.

Reconsideration and withdrawal of the rejection under § 102(b) and § 103(a) is respectfully requested.

#### **IV. Conclusion**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

AMENDMENT UNDER 37 C.F.R. § 1.114(c)  
Application No.: 10/568,671

Attorney Docket No.: Q93246

The U.S. Patent and Trademark Office is hereby directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

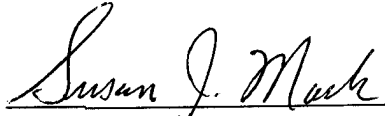
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